

§ 1315.33 Power of attorney.

(a) A registrant may authorize one or more individuals, whether or not located at his registered location, to sign certifications required under § 1315.32(h) on the registrant's behalf by executing a power of attorney for each such individual. The registrant shall retain the power of attorney in the files, with certifications required by § 1315.32(h), for the same period as any certification bearing the signature of the attorney. The power of attorney must be available for inspection together with other certification records.

(b) A registrant may revoke any power of attorney at any time by executing a notice of revocation.

(c) The power of attorney and notice of revocation must be similar to the following format:

Power of Attorney for certifications of quota for procurement of ephedrine, pseudoephedrine, and phenylpropanolamine

____ (Name of registrant)
 ____ (Address of registrant)
 ____ (DEA registration number)

I, _____ (name of person granting power), the undersigned, who am authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint _____ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to sign certifications of quota for procurement of ephedrine, pseudoephedrine, and phenylpropanolamine in accordance with Part 1315 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney must lawfully do or cause to be done by virtue hereof.

____ (Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

____ (Signature of attorney-in-fact)

Witnesses:

1. _____
 2. _____

Signed and dated on the ____ day of __, (year), at _____.

Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

____ (Signature of person revoking power)

Witnesses:

1. _____
 2. _____

Signed and dated on the ____ day of __, (year), at _____.

(d) A power of attorney must be executed by the person who signed the most recent application for DEA registration or reregistration; the person to whom the power of attorney is being granted; and two witnesses.

(e) A power of attorney must be revoked by the person who signed the most recent application for DEA registration or reregistration, and two witnesses.

[73 FR 73555, Dec. 3, 2008]

§ 1315.34 Obtaining an import quota.

(a) Any person who is registered to import ephedrine, pseudoephedrine, or phenylpropanolamine, or whose requirement of registration is waived pursuant to § 1309.24(c) of this chapter, and who desires to import during the next calendar year any ephedrine, pseudoephedrine, or phenylpropanolamine or drug products containing these chemicals, must apply on DEA Form 488 for an import quota for the chemical. A separate application must be made for each chemical desired to be imported.

(b) The applicant must provide the following information in the application:

(1) The applicant's name and DEA registration number.

(2) The name and address of a contact person and contact information (telephone number, fax number, e-mail address).

(3) Name of the chemical and DEA Chemical Code number.

(4) Type of product (bulk or finished dosage forms).

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(5) For finished dosage forms, the official name, common or usual name, chemical name, or brand name, NDC number, and the authority to market the drug product under the Federal Food, Drug and Cosmetic Act of each form to be imported.

(6) The amount requested expressed in terms of base.

(7) For the current and preceding two calendar years, expressed in terms of base:

(i) Distribution/Sales—name, address, and registration number (if applicable) of each customer and the amount sold.

(ii) Inventory as of December 31 (each form—bulk, in-process, finished dosage form).

(iii) Acquisition—imports.

(c) For each form of the chemical (bulk or dosage unit), the applicant must state the quantity desired for import during the next calendar year.

(d) DEA Form 488 must be filed on or before April 1 of the year preceding the calendar year for which the import quota is being applied. Copies of DEA Form 488 may be obtained from the Office of Diversion Control Web site, and must be filed with the Drug & Chemical Evaluation Section. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(e) The Administrator may at his discretion request additional information from an applicant.

(f) On or before July 1 of the year preceding the calendar year during which the quota shall be effective, the Administrator shall issue to each qualified applicant an import quota authorizing him to import:

(1) All quantities of the chemical necessary to manufacture products that registered manufacturers are authorized to manufacture pursuant to § 1315.23; and

(2) Such other quantities of the chemical that the applicant has applied to import and that are consistent with his past imports, the estimated medical, scientific, and industrial needs of the United States, the establishment and maintenance of reserve stocks, and the total quantity of the chemical that will be produced.

[72 FR 37448, July 10, 2007, as amended at 75 FR 10684, Mar. 9, 2010]

§ 1315.36 Amending an import quota.

(a) An import quota authorizes the registered importer to import up to the set quantity of ephedrine, pseudoephedrine, or phenylpropanolamine and distribute the chemical or drug products on the DEA Form 488. An importer must apply to change the quantity to be imported.

(b) Any person to whom an import quota has been issued may at any time request an increase in the quota quantity by applying to the Administrator with a statement showing the need for the adjustment. The application must be filed with the Drug & Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The Administrator may increase the import quota of the person if and to the extent that he determines that the approval is necessary to provide for medical, scientific, or other legitimate purposes regarding the chemical. The Administrator shall specify a period of time for which the approval is in effect or shall provide that the approval is in effect until the Administrator notifies the applicant in writing that the approval is terminated.

(c) With respect to the application under paragraph (b) of this section, the Administrator shall approve or deny the application within 60 days of receiving the application. If the Administrator does not approve or deny the application within 60 days of receiving it, the application is deemed to be approved and the approval remains in effect until the Administrator notifies the applicant in writing that the approval is terminated.

[72 FR 37448, July 10, 2007, as amended at 75 FR 10685, Mar. 9, 2010]

Subpart E—Hearings

§ 1315.50 Hearings generally.

The procedures for the hearing related to assessment of annual needs or to the issuance, adjustment, suspension, or denial of a manufacturing, procurement, or import quota are governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559)